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| Substitute Form PTO-1449<br>(Modified)   | U.S. Department of Commerce<br>Patent and Trademark Office | Attorney's Docket No.<br>06275-0188002 | Application No.<br>10/665,240 |
| <b>Information Disclosure Statement<br/>by Applicant</b><br>(Use several sheets if necessary)<br>(37 CFR §1.98(b)) |  | Applicant<br>Tommy Ekstrom             |                               |
|  |  | Filing Date<br>September 19, 2003      | Group Art Unit<br>1617        |

| U.S. Patent Documents |           |                 |                  |           |       |          |                            |
|-----------------------|-----------|-----------------|------------------|-----------|-------|----------|----------------------------|
| Examiner Initial      | Desig. ID | Document Number | Publication Date | Patentee  | Class | Subclass | Filing Date If Appropriate |
|                       | 1         | 5,684,199       | 11/04/1997       | Francotte |       |          |                            |

| Foreign Patent Documents or Published Foreign Patent Applications |           |                 |                  |                          |       |          |             |    |
|---|-----------|-----------------|------------------|--------------------------|-------|----------|-------------|----|
| Examiner Initial  | Desig. ID | Document Number | Publication Date | Country or Patent Office | Class | Subclass | Translation |    |
|   |           |                 |                  |                          |       |          | Yes         | No |
|   | 2         | WO 92/11280     | 07/09/1992       | WIPO                     |       |          |             |    |
|   | 3         | WO 98/15280     | 04/16/1998       | WIPO                     |       |          |             |    |
|   | 4         | EP1085877       | 12/16/1999       | Europe                   |       |          |             |    |
|   | 5         | WO99/64014      | 12/16/1999       | WIPO                     |       |          |             |    |
|   | 6         | EP0613371       | 03/06/2002       | Europe                   |       |          |             |    |

| Other Documents (include Author, Title, Date, and Place of Publication) |           |  |
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| Examiner Initial  | Desig. ID | Document   |
|   | 7         | Ankerst et al., "Tolerability of a High Dose of Budesonide/Formoterol in a Single Inhaler in Patients with Asthma," manuscript (24 pages), as submitted for publication to Pulm. Pharm. Ther. with letter dated February 6, 2003 to the EPO, later published as Vol. 16(3), pages 147-151 (2003).                                  |
|   | 8         | Ankerst et al., "Tolerability of a High Dose of Budesonide/Formoterol in a Single Inhaler in Patients with Asthma," Pulm. Pharm. Ther. Vol. 16(3):147-151 (2003) (abstract only).  |
|   | 9         | Bjermer et al., "Long-acting $\beta_2$ -agonists: how they are used in an optimal way?," Respiratory Medicine, Vol. 91, pages 587-591 (1997).  |
|   | 10        | Bourbeau et al., "Randomised controlled trial of inhaled corticosteroids in patients with chronic obstructive pulmonary disease", Thorax, Vol. 53, pages 477-482 (1998).   |
|   | 11        | Clinical Practice Guidelines, Expert Panel Report 2, Guidelines for the Diagnosis and Management of Asthma, NIH Publication No. 97-4051, July 1997.  |
|   | 12        | Corden and Rees, "The effect of oral corticosteroids on bronchodilator responses in COPD," Respiratory Medicine, Vol. 92, pages 279-282 (1998).  |
|   | 13        | Haughney et al., "Adjustable maintenance treatment with budesonide/formoterol combination rapidly improves and maintains quality of life in asthma patients," European Respiratory Society Annual Congress (ERS) Stockholm, September 14-18, 2002, Poster Presentation, P379, submitted to EPO with letter dated February 6, 2003. |
|   | 14        | Ind et al., "Managed Adjustable closing of budesonide/formoterol combination provides equivalent asthma control to fixed dosing at a lower overall dose," European Respiratory Society Annual Congress (ERS) Stockholm, September 14-18, 2002, Poster Presentation, P2450, submitted to EPO with letter dated February 6, 2003.    |
|   | 15        | Letter from AstraZeneca to EPO dated 6 February 2003 in EP Application 99930103.9.   |

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| Examiner Signature   | Date Considered |
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| Examiner Initial  | Desig. ID | Document   |
|   | 16        | Lipworth, "A Single High Dose of Budesonide Rapidly Reverses Bronchoprotective Subsensitvity and B2-Adrenoceptor Down-Regulation in Patients Receiving Regular Formoterol," J. Allergy Clin. Immunol., Page S152, Section 629, January 1998.   |
|   | 17        | Lipworth, "Airway Subsensitvity with Long-Acting $\beta_2$ -Agonists," Drug Safety, Vol. 16(5), pages 295-308 (1997).  |
|   | 18        | Lipworth et al., "Effects of Treatment with Formoterol on Bronchoprotection against Methacholine," Amer. J. Med., Vol. 104, pages 431-438 (1998).  |
|   | 19        | Löfdahl et al., "Long-acting $\beta_2$ -adrenoceptor agonists: a new perspective in the treatment of asthma," The European Respiratory Journal, Vol. 4, pages 218-226 (1991).  |
|   | 20        | O'Byrne et al., "Additive Effects of Budesonide and Formoterol in Reducing Severe Asthma Exacerbations over 12 Months," abstract of presentation given at the June 1-5, 1997, Annual Meeting of Allergology and Clinical Immunology, published as abstract 266 in Allergy 52, Supp. 37-89 (1997).                              |
|   | 21        | Olsson et al., "Adjustable maintenance treatment of asthma with budesonide and formoterol in a single inhaler," European Respiratory Society Annual Congress (ERS) Stockholm, September 14-18, 2002, Poster Presentation, P2451, submitted to EPO with letter dated February 6, 2003.  |
|   | 22        | Paggiaro et al., "Multicentre randomised placebo-controlled trial of inhaled fluticasone propionate in patients with chronic obstructive pulmonary disease," The Lancet, Vol. 351, pages 773-780 (1998).   |
|   | 23        | Price et al., "Budesonide/formoterol with an adjustable maintenance plan costs less and is as effective as fixed dosing," European Respiratory Society Annual Congress (ERS) Stockholm, September 14-18, 2002, Poster Presentation, P2452, submitted to EPO with letter dated February 6, 2003.                                |
|   | 24        | Rosenhall et al., "Efficacy, safety and cost of budesonide/formoterol in a single inhaler compared with budesonide plus formoterol as separate inhalers", European Respiratory Society Annual Congress (ERS) Stockholm, September 14-18, 2002, Poster Presentation, P388, submitted to EPO with letter dated February 6, 2003. |
|   | 25        | Scrip, The Dialog Corporation, 1562, page 21 (31 October 1990).  |
|   | 26        | Sung et al., "Randomized, Controlled Trial of Inhaled Budesonide as an Adjunct to Oral Prednisone in Acute Asthma", Academic Emergency Medicine, Vol. 5(3), pages 209-212 (1998).  |
|   | 27        | Wempe et al., "Effects of corticosteroids on bronchodilator action in chronic obstructive lung disease," Thorax, Vol. 47, pages 616-621 (1992).  |
|   | 28        | Decision of the EPO Opposition Division regarding patent EP-B-1210943, dated December 5, 2008.   |
|   | 29        | Statement of Grounds of Opposition to patent EP1085877 by Vectura Limited, received at the EPO on December 17, 2008.   |
|   | 30        | Statement of Grounds of Opposition to patent EP1085877 by Generics Limited, received at the EPO on December 19, 2008.  |
|   | 31        | Statement of Grounds of Opposition to patent EP1085877 by Norton Health Care Limited, received at the EPO on December 19, 2008   |
|   | 32        | Statement of Grounds of Opposition to patent EP1085877 by Ratiopharm GmbH, received at the EPO on December 17, 2008, translation attached.   |
|   | 33        | Response by Astra to EPO, dated November 22, 1995.   |

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| Examiner<br>Initial  | Desig.<br>ID | Document  |
|  | 34           | "What You Should Know About Symbicort Turbohaler?," AstraZeneca, May 2001, 4 pages. |

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